

April 27, 2004

Susan D. Brienza
(303) 894-6146
sbrienza@pattonboggs.com

Via Federal Express and
Via Facsimile: 301-436-2636

Linda Pellicore, Ph.D., and Tanya Jackson
Office of Nutritional Products, Labeling & Dietary Supplements
Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Clarification for NDI Notification for Phyto-derived Ceramides

Dear Dr. Pellicore and Ms. Jackson:

Thank you for your telephone call of today, and the specific guidance for replying to the fax of Tanya Jackson, which was apparently sent on April 25th and which I received yesterday. Per your request, this letter provides a few clarifications and additions for our recently-filed NDI Notification for Phyto-derived Ceramides.

1. On behalf of my client, Soft Gel Technologies, Inc., I am restating that the subject of this Notification is Ceramides as derived from either rice or from wheat, specifically wheat germ oil. I note that in our conversation of today there was no disagreement that ceramides derived from rice and from wheat are chemically identical.

2. On the label of the proposed dietary supplement containing phyto-derived ceramides, in the listing of the dietary ingredient in the Supplement Facts box, the plant source of the ceramides will be declared, whether rice or wheat-based. In the case of the use of wheat-derived ceramides, we note for your consideration that the source is wheat germ oil (rather than wheat flour or wheat gluten) which my client believes poses much less of a potential allergen problem. Nonetheless, for a supplement containing wheat-derived ceramides the proposed label will contain the following cautionary language, printed in bold and prominent type: **"WARNING: This product contains ceramides which are derived from wheat germ oil. Do not take this product if you are allergic to wheat in any form."**

3. The taxonomy of the plant sources for the ceramides which are the subject of this Notification are as follows, as provided in the GRIN database on the USDA website:

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Oryza sativa L. [*Poaceae*]

Genus: *Oryza* section: *Oryza* series: *Oryza*

Family: *Poaceae* (alt. *Gramineae*) subfamily: *Ehrhartoideae* tribe: *Oryzeae*.

Triticum aestivum L. [*Poaceae*]

Genus: *Triticum*

Family: *Poaceae* (alt. *Gramineae*) subfamily: *Pooideae* tribe: *Triticeae*.

I understand from our telephone conversation of today that the added information provided does not re-set or delay the 75-day clock for this NDI Notification. If you should have any further questions about this Notification submission, please contact me at 303-894-6146, or at sbrienza@pattonboggs.com. Thank you in advance.

Sincerely,

Susan D. Brienza

Susan D. Brienza

SDB:sdb

cc: Vicky Lutwak, via e-mail